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K070392

510(k) Summary for the
Lutronic Corporation MOSAIC Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Lutronic Corporation #403-2,3,4, Ilsan Technotown 1141-1 Baeksok-Dong, Ilsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	July 11, 2007

2. **Names**

Device Name:	MOSAIC Laser System
Classification Name:	Laser Instrument, Surgical, Powered Product Code: GEX Panel : General & Plastic Surgery

3. **Predicate Devices**

The MOSAIC Laser System is substantially equivalent to a combination of the Fraxel SR Laser System (K053047) and the Fraxel II SR Laser System and Accessories (K060310).

4. **Device Description**

The MOSAIC Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The MOSAIC produces a beam of coherent infrared (1550 nm) light. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different handpiece tip (5 mm, 6 mm, 8 mm, and 10 mm).

The system console is the heart of the MOSAIC Laser System and contains the optical system (Er-GLASS Fiber Laser Module), Touch LCD, handpiece, system control module with an embedded processor, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the Touch LCD.

5. Indications for Use

The MOSAIC Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue.

6. Performance Data

Human and animal performance data was provided which documented that the histological response to the MOSAIC was substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

O'Connell Regulatory Consultants, Inc.
% Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K070392
Trade/Device Name: MOSAIC Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general
And plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 2, 2007
Received: July 3, 2007

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070392

Device Name: MOSAIC Laser System

Indications for Use:

The MOSAIC Laser System is indicated for dermatological procedures requiring the coagulation of soft tissue.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070392